REMARKS

The nonelected claims 17, 19-24, 26-30, 33 and 35-40 have been cancelled as required by the Examiner. This cancellation is being made without prejudice.

Claim 1 has been amended to delete "comprising" as required by the Examiner.

The Examiner has again rejected claims 1-16,18,25,31,32 and 34 under 35 U.S.C. 103(a) as being unpatentable over the Sundstrom patent.

With respect first to the compounds used in the Sundstrom patent, these compounds are long chain polypeptides containing the chain SEQ.ID No.1, set forth in Figure 1. This chain contains the following amino acids linked together in the precise sequence shown in Fig. 1.: serine, isoleucine, glutamine, phenylalanine, histidine, tryptophan, lysine, asparagine, leucine, glycine, threonine, aspartic acid, arginine, and alanine. Isoleucine comprises only seven of the 148 amino acids required in the sequence.

It is respectfully submitted that this polypeptide sequence does not fall within the term "composition (or compound) consisting essentially of isoleucine". The Sundstrom amino acid polypeptide sequence consists essentially of amino acids other than isoleucine.

Moreover, there is no disclosure in Sundstrom of isoleucine itself or active isomers or analogs of isoleucine (see page 2, line 20-page 3, line 3 of the present specification) to which the present claims are limited. The term "isoleucine" does not include polypeptides containing isoleucine (which is present in the polypeptide as a reaction product).

The Examiner contends on page 5 of the Final Rejection that the prior art teaches the generic concept of the use of isoleucine ... since isoleucine is within the group of polypeptides disclosed at columns 10 and 16". However, the teachings in columns 10 and 16 all refer to polypeptide sequences of linked amino acids, not isoleucine itself. Polypeptide sequences are not a "generic concept of the use of isoleucine", but rather a markedly different chemical entity containing small quantities of isoleucine as a reaction product with large quantities of other amino acids to form a precise linked sequence of amino acids. The isoleucine used in the present invention is not chemically linked with other amino acids especially not in long chain polypeptides.

In the "Response to Arguments" on page 6, last paragraph, the Examiner contends that the present specification and claims do not exclude the polypeptides or the amino acids defined in Sundstrom. This contention is respectfully controverted. As discussed above, the specification limits the term "isoleucine" to isoleucine and active isomers and analogs of isoleucine (page 2, line 20-page 3, line 3). The present claims are so limited. The above terminology does not include polypeptide sequences.

The Examiner next contends that the burden is shifted to Applicant to show that the addition of polypeptides or amino acids is detrimental to the formulation. It is not agreed that Applicant has any such burden. Applicant is not required by any patent law or practice to compare a claimed compound with an entirely different chemical entity in which the claimed compound is present as a reaction product, particularly where the claimed compound comprises a very small component of the disclosed reaction product (the reaction product being the reaction product of fourteen amino acids in which

isoleucine is present as only 7 of 148 amino acids required to be present in a precise order in the polypeptide chain).

Concerning the Examiner's arguments with respect to the mechanism of action of Sundstrom's polypeptides, this is respectfully submitted to be irrelevant, since the compounds in the Sundstrom reference are not the isoleucine compounds of the present invention. Hence, the respective mechanisms of action are not relevant to the issue of patentability.

Moreover, the mechanisms of action of the polypeptide in the Sundstrom patent is quite different from the mechanism of action of isoleucine in the present invention.

Sundstrom's invention relates to blocking an enzyme which is believed to cause bacteria to remain stably attached to eukaryotic cells, i.e. the enzyme is believed to chemically crosslink bacteria to the cell surface. In the present invention, isoleucine blocks the binding of microorganisms to the cells by means of a single entity amino acid which exhibits no chemical activity, i.e. is nonreactive and is chemically quite stable. Isoleucine does not react with enzymes.

Sundstrom describes the use of a specific polypeptide to compete with bacteria as a substrate for the enzyme, serving in effect as a bacteria decoy, competing with the bacteria by not allowing the bacteria to couple with the enzyme. The present invention in effect uses isoleucine as an antibody against the enzyme to block the enzyme from coupling the surface of the cell to the microorganism.

In addition, isoleucine can be taken orally and is not degraded by the action of proteases, whereas peptides (including Sundstrom's) will be degraded (digested) if taken orally. Isoleucine is an essential amino acid, having a well established record of safety,

regarded by the FDA as a GRAS substance. This amino acid is a simple compound which is inexpensive, readily available, and which requires no synthetic preparative pathway. Sundstrom's polypeptide must be synthesized (fragmented from a fungal source). Also Sundstrom's polypeptide has unknown safety properties.

It is submitted to be clearly unobvious to use isoleucine itself based on the teachings of Sundstrom of a long chain polypeptide in which very minor quantities of isoleucine are present.

The above discussion is applicable to all of the present claims. However, with respect to the dependent claims, claims 2-4 disclose microbial blocking quantities of isoleucine not disclosed by Sundstrom.

Claim 7 limits the composition to a pure powder of L (+) isoleucine and/or DL-isoleucine, clearly not disclosed by Sundstrom.

Claims 11-16, 18, 25, 31,32 and 34 claim compositions comprising isoleucine and at least one additional pharmacologically active substance, also clearly not disclosed by Sundstrom. Moreover, claims 14, 16, 31 and 34 are directed to formulations not disclosed by Sundstrom.

In view of the above discussion, allowance of claims 1-16, 18, 25, 31, 32 and 34 is respectfully solicited.

Respectfully submitted,

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